IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	Civil Action No. 1:08-07231
Plaintiffs,	Consolidated with Civil Action No. 1:09-cv-6053
v.	Judge Robert M. Dow Jr.
APOTEX INC. and APOTEX CORP.,	Magistrate Judge Martin C. Ashman
Defendants.	

APOTEX'S SUPPLMENTAL MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS

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INTRODUCTION

In accordance with the Court's instruction at the hearing on October 21, 2009, Apotex Inc. and Apotex Corp. (collectively, "Apotex") respectfully submit this Supplemental Memorandum of Law in Opposition to Plaintiffs' Motion to Dismiss Defendants' Counterclaims.

FACTUAL BACKGROUND

At the hearing on October 21, the Court instructed the parties to submit a short supplemental brief addressing any new factual developments since the original briefing on Plaintiffs' motion to dismiss. Since that time, an important new fact emerged: Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (collectively, "Pfizer") have asserted U.S. Patent No. 5,969,156 ("'156 patent") against subsequent ANDA-filers, Mylan Inc. and Matrix Laboratories ("Mylan and Matrix"), in actions filed in the United States District Courts for the District of Delaware and the Northern District of West Virginia on June 15, 2009 (*See* Supp. Alul Decl., Ex. A., Pfizer's Compl., *Pfizer Inc. v. Mylan Inc.*, No. 1:09-cv-441-JJF (D. Del. June 15, 2009); *id*. at Ex. B, Pfizer's Compl., *Pfizer Inc. v. Mylan Inc.*, No. 1:09-cv-79-IMK (N.D.W.Va. June 15, 2009))—only a couple of months after Pfizer told this Court, in its opening brief, that Apotex cannot reasonably expect to be sued on that patent (and others), precisely because Pfizer has never asserted those patents against *any* ANDA-filer.

In addition, Pfizer now apparently purports to rely on an unpublished opinion from New Jersey in *Teva Pharms. USA, Inc. v. Eisai Co.*, No. 08-2344, 2009 WL 2905534 (D.N.J. Sept. 9, 2009) ("*Eisai*"). The *Teva* case is clearly distinguishable and does not at all detract from the fact that this Court has subject matter jurisdiction over Apotex's counterclaims under Article III.

SUPPLEMENTAL ARGUMENT

I. Pfizer Has Shown That It Will Assert The '104, '156, And '971 Patents Against Generic Competitors By Asserting The '156 Patent Against Mylan And Matrix, Subsequent ANDA-Filers.

In its opening brief, Pfizer argued that there is no subject matter jurisdiction over counts III-VIII of Apotex's counterclaims, which seek a declaratory judgment of invalidity and non-infringement of the '104, '156, and '971 patents, because Apotex cannot reasonably expect Pfizer to assert any of these patents:

> Apotex cannot have reasonable apprehension that Pfizer will assert the Unasserted Patents in the future.
>
> Although all four *atorvastatin* ANDA-filers have made paragraph IV certifications against the Unasserted Patents, Pfizer has never asserted those patents against them. In fact, in the six years that generic manufacturers have been filing *atorvastatin* ANDAs, Pfizer has consistently asserted only the '995 patent.

(Docket Item No. ("D.I.") 56, Pls.' Br. 13-14) (italics and underscore original) (footnote omitted). But only a couple of months after filing its motion to dismiss, Pfizer asserted the '156 patent against Mylan and Matrix (*see* Supp. Alul Decl., Exs. A-B), subsequent ANDA-filers—vastly undercutting any claim by Pfizer that Apotex "cannot have a reasonable apprehension that Pfizer will assert the Unasserted Patents . . . ." (D.I. 56, Pls.' Br. 13). In suing Mylan and Matrix on the '156 patent, Pfizer has shown that it will do whatever takes—and assert whatever patents it has—in order to protect its monopoly on atorvastatin. This patent uncertainty alone is sufficient Article III injury, and is exactly the "type of uncertainty of legal rights that the ANDA declaratory judgment action was enacted to prevent." *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007) ("*Novartis*").

In addition to Pfizer's affirmative declaration that "a claim of patent infringement could reasonably be asserted" against Apotex with respect to the '104, '156, and '971 patents (D.I. 68, Apotex's Opp'n Br. 14), and Pfizer's general counsel's statement that these patents could be

used to "block[] generics" (*Id.* at 13 n.8, 17), Pfizer has now conclusively demonstrated that it will actually use these patents to block generic entry. This is further proof that there is subject matter jurisdiction to adjudicate Apotex's declaratory judgment claims regarding the '104, '156, and '971 Orange Book patents.

II. Pfizer's Reliance On *Teva v. Eisai* Is Seriously Misplaced, And Does Not Defeat Subject Matter Jurisdiction Over The Unasserted Orange Book Patents Here.

Pfizer now purports to rely on the District of New Jersey's unpublished decision in *Teva v. Eisai*, suggesting that *Eisai* somehow eliminates any Article III controversy under the facts of *this* case. Pfizer is mistaken. Indeed, it is curious why Pfizer even bothers to cite *Eisai* given the strikingly different facts and reasoning at issue there. Most notably, and as Pfizer disingenuously omits, the patents at issue in *Eisai* either were *disclaimed* or the subject of *binding covenants-not-to-sue*. *See Eisai*, 2009 WL 2905534, at *4-*5. Either way, as the court there found, "Eisai has no right to enforce the DJ patents," and so the declaratory plaintiff "faces no restraint on its ability to market generic donepezil based on the potential that Eisai may bring suit to prevent such marketing based on the DJ patents." *Id*. at *7.

In stark contrast here, Pfizer admittedly has *not* disclaimed any of the unasserted Orange Book patents, and nor has it given anyone a binding covenant-not-to-sue. Quite the contrary, Pfizer has intentionally preserved the right to assert those patents against Apotex and others—and, as noted above, Pfizer has in fact asserted one of those patents against generic ANDA applicants Mylan and Matrix.[1] Unlike *Eisai*, there remains a very real possibility—if not a virtual certainty given the action against Mylan/Matrix—that Pfizer could assert against Apotex the '104, '156, and '971 patents, which is precisely the "restraint" that gives rise to an Article III

[1] Apotex does not concede that even a binding covenant would moot the controversy here. But that, of course, is not a question before this Court, because Pfizer has neither provided such a covenant, nor disclaimed the unasserted patents. To the contrary, Pfizer retains the ability to assert those patents at any time, just as it has done to Mylan/Matrix.

controversy under the Federal Circuit's binding decision in *Novartis*. *Eisai*, therefore, could not be further afield, and in fact is distinguishable for the same reasons as all of the other cases cited by Pfizer in its moving papers. Just as importantly, *Eisai* certainly cannot trump the Federal Circuit's binding precedent in *Novartis*, which squarely holds that a court has subject matter jurisdiction to adjudicate unasserted Orange Book patents under facts identical to those here. *Novartis*, 482 F.3d at 1345-46.

It also bears noting that delay of FDA approval of the ANDA in question in *Eisai* did not result from an inability of the subsequent-filer (Teva, through Gate—an unincorporated division) to trigger the first-filer's (Ranbaxy) exclusivity, but rather was the result of (a) generic exclusivity held by the subsequent-filer (Teva) through a separate ANDA, and (b) a preliminary injunction in place against the subsequent-filer. *See Eisai*, 2009 WL 2905534, at *11-*12. Here, of course, there is no court order, based on a showing of reasonable likelihood of success or otherwise, precluding Apotex Inc. from going to market with its generic atorvastatin prior to expiration of the earlier-expiring patents that Pfizer has listed for Lipitor®, including U.S. Patent No. RE40,667 E ("'667 patent").[2] And Apotex Inc.'s paragraph III certification to U.S. Patent No. 4,681,893 is not a court order, preliminary injunction or stipulation of validity, but rather an administrative certification that can be changed at any time. And in any event, it has no relevance here under any of the cases that Pfizer relies on, all of which involved binding covenants-not-to-sue and/or patent disclaimers, which admittedly are not present here. In the end, the '104, '156, and '971 patents can still be asserted by Pfizer, and indeed have been, and remain a potential restraint on Apotex's ability to market a competing generic drug. Indeed,

[2] It is Apotex's position that U.S. Patent No. 5,273,995 ("'995 patent"), which, together with the '667 patent, make up the patents-in-suit in this action, was surrendered to the USPTO upon its reissuance as the '667 patent. Apotex has filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) directed to those portion of Pfizer's first amended complaint that assert the '995 patent. (*See Pfizer Inc. v. Apotex Inc.*, No. 09-cv-6053 (N.D. Ill.), D.I. 34).

holding these patents over Apotex's head, like a modern-day sword of Damocles, is exactly the "type of uncertainty of legal rights that the ANDA declaratory judgment action was enacted to prevent." *Novartis*, 482 F.3d at 1345.

CONCLUSION

An actual controversy exists between Apotex and Pfizer with respect to the '104, '156, and '971 patents under Article III and controlling precedent. The fact that Pfizer has recently asserted one of the very patents Pfizer said it would not assert only reinforces the actual controversy between Apotex and Pfizer. The Court should deny Pfizer's motion to dismiss.

Dated: November 12, 2009.

Respectfully submitted,

APOTEX INC. AND APOTEX CORP.

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CERTIFICATE OF SERVICE

I, Andrew M. Alul, hereby certify that this 12th day of November, 2009, I caused a true and correct copy of the foregoing APOTEX'S SUPPLEMENTAL MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS to be served by the ECF filing system of the Northern District of Illinois which will send notification of such filing via electronic mail to all counsel of record.

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